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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/181,027	10/27/1998	THOMAS HAAF	A-65680-4/RF	9418

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FLEHR HOHBACH TEST
ALBRITTON & HERBERT
FOUR EMBARCADERO CENTER
SUITE 3400
SAN FRANCISCO, CA 94111

EXAMINER	
BRUSCA, JOHN S	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 10/24/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/181,027	RADDING ET AL.	
	Examiner	Art Unit	
	John S. Brusca	1631	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *08 October 2002*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☒ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☒ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *40-44 and 47-55*.

Claim(s) withdrawn from consideration: _____.

8.☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

John S. Brusca
Primary Examiner
Art Unit: 1631

Continuation of 5. does NOT place the application in condition for allowance because:

The applicants point to supplied publication WO 93/22443 as providing an enabling description in the prior art of gene therapy that supports the claimed invention. However, inspection of WO 93/22443 shows that it does not disclose a working example of gene therapy. Instead it discloses a working example of gene mutation in cultured cells.

The applicants argue that Orkin et al. does not show lack of enablement in the prior art for gene therapy. However Orkin does not show over 100 approved gene therapy protocols as the applicants argue, Instead Orkin discusses clinical trials of gene therapy as follows: "Although widely referred to as 'clinical trials,' gene transfer protocols to date are in truth small scale clinical experiments. Such explorator studies are meant to test the feasibility and safety of administering particular vectors and to evaluate the effects of expressing specific gene products. Because these studies have not been designed to measure efficacy, they do not include sufficient controls to evaluate the true merits of gene therapy or compare this approach with conventional approaches to the same disease.". Orkin et al. goes on to discuss the problems with available gene therapy vectors, as summarized in Table 1. The applicants have failed to provide evidence that the prior art enables gene therapy.

The applicants state that the specification provides written description for human cells as claimed in claims 47-55. However, the applicants have failed to point to description of human cells comprising the claimed recombinant constructs in the instant specification an the rejection for lack of written description is maintained.